DATE OUT: 12/JAN/2011

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: TGAI [ ]; MUP [ ]; EUP [X]
BARCODE NO.: D378915 **REG./FILE SYMBOL NO.:** 2517-26
PRODUCT NAME: Double Duty Flea & Tick Spray **MRID NO.:** 481050-01
COMPANY NAME: Sergeant's Pet Care Products, Inc. **ACTION CODE:** 676
CONTRACTOR: CSC **PROJECT CODE:** PRD-14 OPII

FROM: Jolene Trujillo, Biologist
Risk Management and Implementation Branch V
Product Re-evaluation Division (7508P)

TO: Maia Tatinclaux, CRM
Risk Management and Implementation Branch V
Product Re-evaluation Division (7508P)

INTRODUCTION:
A Reregistration Eligibility Decision (RED), Case number 2580, was issued on June 7, 2006 for the Active Ingredient (AI) Pyrethrins. According to the RED, the generic data base supporting the reregistration of Pyrethrins for currently registered uses has been reviewed and found to be substantially complete.

In the 8-month response to the Pyrethrins RED, Sergeant's Pet Care Products, Inc. provided two Confidential Statements of Formula (CSFs) for the basic and alternate formulations, both dated 3/5/2010; EPA Form 8570-35 (Data Matrix), dated 5/5/2010; EPA Form 8570-36 (Summary of the Physical/Chemical Properties (PR Notice 98-1)), dated 5/24/2010; EPA Form 8570-37 (Self-Certification Statement for the Physical/Chemical Properties (PR Notice 98-1)), dated 5/20/2010; a draft label (pin-punched 05·26·10); and one study (MRID No. 481050-01). The registrant is requesting reregistration of their product, Double Duty Flea & Tick Spray, EPA Reg. No. **2517-26**.

FINDINGS:
1. EPA Reg. No. **2517-26** is an end-use insecticide, containing the active ingredients, Pyrethrins, Piperonyl butoxide (PBO), and N-Octyl bicycloheptene dicarboximide (MGK 264), with label claim nominal concentrations of 0.06%, 0.12%, and 0.20%, respectively. The product is an insecticide for use in killing fleas, lice, and ticks and repelling flies, gnats, and mosquitoes. The product is for use on pets. The product is produced by a non-integrated system.

2. The CSF for the basic formulation is acceptable as presented. The nominal concentrations of the active ingredients agree with that on the draft label, meeting PR Notice 91-2. The certified limits for the active ingredients and inert ingredients are acceptable in accordance with 40 CFR §158.175(b)(2). All ingredients listed on the CSFs are cleared for use in pesticide formulations.

3. Except for Finding 4a, the data reported in MRID No. 481050-01 satisfy the product chemistry requirements as specified in 40 CFR §158.155, 158.160, 158.165, 158.167, 158.175, and 158.180 (the new 40 CFR section numbers are 158.320, 158.325, 158.335, 158.340, 158.350, and 158.355, respectively) which pertain to Product Identity and Composition, Description of Materials Used to Produce the Product, Description of Formulation Process, Discussion of Formation of Impurities, Certified Limits, and Enforcement Analytical Method.

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Except for Finding 4b, the data also satisfy the product chemistry requirements as specified in 40 CFR §158.190 (the new 40 CFR number is 158.310) which pertain to the Physical and Chemical properties of the product.

4a. The requirements concerning Guideline 830.1800 (Enforcement Analytical Method) are not fully satisfied. The "method" in MRID No. 481050-01 provides a description of the instrument system and method parameters for the PBO and Pyrethrin portions of the product only. The "method" needs to be revised to include procedures for the analysis of MGK 264. A revised methodology might include sections such as Summary, Scope, Equipment (i.e., Apparatus, Reagents), Analytical Procedure, and Calculations.

4b. The requirements concerning Guidelines 830.6317 (Storage Stability) and 830.6320 (Corrosion Characteristics) are not satisfied. Results for a minimum of 1 year from a GLP-compliant storage stability and corrosion characteristics study must be provided. The concentration of the active ingredients in the product must be determined at the beginning of the test period and every 3 months thereafter for a period of 1 year. The product should be tested in its commercial packaging.

5. The Ingredients Statement on the draft label is acceptable as per 40 CFR §156.10(g) and PR Notices 91-2 and 97-6. No data are present to trigger the need for a Physical or Chemical Hazards Statement. The Storage and Disposal Statements are acceptable in accordance with 40 CFR §156.10(i)(2)(ix) and PR Notice 83-3.

NOTE TO CRM: The labeling issues should be addressed during label review.

NOTE TO PM: It appears that the registrant has modified the Pesticide Storage subheading statements to comply with PR Notice 2007-4. PRD/RMIBV defers to RD the acceptability of these statements.

CONCLUSIONS:

Except for findings 4a and 4b the registrant has satisfied the product chemistry requirements for the reregistration of EPA Reg. No. **2517-26**.

Product Chemistry Data

Subgroup A: Guideline Series 830.1550 - 830.1800 (40 CFR §158.320 - 158.355)
Product Identity, Composition, and Analysis

Guideline Reference No. (GRN) / Title 830	40 CFR §	MRID Number	Data Fulfilled
830.1550 Product Identity and Composition	158.320	481050-01 and CSFs	Y
830.1600 Description of Materials Used to Produce the Product	158.325	481050-01 and CSFs	Y
830.1620 Description of Production Process	158.330	*[Not required for products produced by a non-integrated system]*	NR
830.1650 Description of Formulation Process	158.335	481050-01 and CSFs	Y
830.1670 Discussion of Formation of Impurities	158.340	481050-01	Y
830.1700 Preliminary Analysis	158.345	*[Not required for products produced by a non-integrated system]*	NR
830.1750 Certified Limits†	158.350	481050-01 and CSFs	Y
830.1800 Enforcement Analytical Method	158.355	481050-01	I, U

Subgroup B: Guideline Series 830.6302 - 830.7950 (40 CFR §158.310)
Physical and Chemical Properties

Guideline Reference No. (GRN) / Title 830	Value or Qualitative Description	MRID Number	Data Fulfilled
.6302 Color	*[Not required for end-use products.]*		NR
.6303 Physical State	Liquid	EPA Form 8570-36	Y

Guideline Reference No. (GRN) / Title 830	Value or Qualitative Description	MRID Number	Data Fulfilled
.6304 Odor	*[Not required for end-use products.]*		NR
.6314 Oxidation/ Reduction: Chemical Incompatibility	Not applicable. Contains no oxidizing/ reduction agents.	EPA Form 8570-36	N/A
.6315 Flammability/Flame Extension	Not applicable. Water-based product.	EPA Form 8570-36	N/A
.6316 Explodability	Not applicable. Not potentially explosive based on product composition and experience.	EPA Form 8570-36	N/A
.6317 Storage Stability	To be submitted.	EPA Form 8570-36	G
.6319 Miscibility	Not applicable. Not to be diluted with petroleum solvents.	EPA Form 8570-36	N/A
	The product is ready-to-use (i.e., is to be applied undiluted).	Label	Y
.6320 Corrosion Characteristics	To be submitted.	EPA Form 8570-36	G
.6321 Dielectric Breakdown Voltage	Not applicable. Not for use around electrical equipment	EPA Form 8570-36	N/A
.7000 pH	7.0	EPA Form 8570-36	Y
.7100 Viscosity	2 cps	EPA Form 8570-36	Y
.7300 Density/Relative Density	0.992 g/mL (8.26 lbs/gal)	EPA Form 8570-36	Y

Explanations: Y = Requirement fulfilled; N = Requirement not fulfilled; N/A = Not applicable; G = Data gap; U = Upgradeable; I = Incomplete or in progress; W = Waived; NR = Not required

Manufacturing process information may be entitled to confidential treatment
Product ingredient source information may be entitled to confidential treatment

Confidential Appendix A

830.1550 Product Identity and Composition

EPA Reg. No. **2517-26** is an end-use product produced by a non-integrated system. The product contains the active ingredients, Pyrethrins, PBO, and MGK 264, with label claim nominal concentrations of 0.06%, 0.12%, and 0.20%, respectively. The source of the active ingredients is the registered product, [redacted] Nominal concentrations and upper/lower certified limits are identified in MRID No. 481050-01 and on the CSFs.

830.1600 Description of Materials Used to Produce the Product

The starting materials used in the formulation of EPA Reg. No. **2517-26** are identified in MRID No. 481050-01 and on the CSFs. Technical specifications were not provided; however, MSDSs were found to be available on the Internet for each inert formulation component with the following exception: [redacted]

830.1650 Description of Formulation Process

The formulation process is described in MRID No. 481050-01, as follows:

[redacted]

830.1670 Discussion of Formation of Impurities

A discussion of impurity formation is provided in MRID No. 481050-01.

Carry-over of impurities from the registered active ingredients

No impurities other than those typically present in the technical grade active ingredient or the manufacturing use product (MUP) can reasonably be expected. Those impurities are described in the registration application for the active ingredient source.

Carry-over of impurities in intentionally added inerts
The other ingredients in the product are recognized pesticide formulation ingredients (see CSFs). There are no known or apparent opportunities for introducing impurities of significance from the use of the listed other ingredients.

Reactions occurring during production
The formulation process for the production of this ready to spray end-use formulation does not involve any chemical reactions in which the active ingredients participate. The opportunity for chemical reactions during production is, therefore, judged to be minimal or nonexistent. Based on known chemistry, prior practical experience, and properties described in the Material Safety Data Sheets, neither the active ingredients nor the other ingredients are considered to be strong oxidizing or reducing agents. Neither the active ingredients nor other ingredients in the product are high-energy chemicals.

Post-production reactions
Pyrethrins, MGK 264, and PBO are commodity insecticides on a global basis for at least 20 years. No reports of stability or compatibility have surfaced in the literature. This specific manufacturer has produced the product for several years without reports of stability or change in composition. Based on this analogy and the results of exploratory chemical stability testing, there is no indication of any post-production reaction of any significance.

Migration of packaging materials into the product
Based on typical result with these formulations in commercial packaging, no significant reaction is expected between the active ingredients and the commercial packaging materials which would adversely affect the products.

830.1750 Certified Limits

The CSF for the basic formulation, dated 3/5/2010, provides the following certified limits for the active ingredient source and active ingredients:

Component	Lower Certified Limit	Nominal Concentration	Upper Certified Limit
	% by weight		
[redacted]			
Pyrethrins	(0.054)	(0.06)	(0.066)
PBO	(0.108)	(0.12)	(0.132)
MGK 264	(0.18)	(0.20)	(0.22)

Upper and lower certified limits for the active ingredients and inert ingredients are standard. A signed certification statement was not provided, as requested under Guideline 830.1750(g).

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Product ingredient source information may be entitled to confidential treatment

Pages 7-8 Confidential Statement of Formula may be entitled to confidential treatment